REMARKS

The present invention relates to compositions and methods for treatment of disorders and diseases such as those associated with abnormal cellular proliferation, angiogenesis, inflammation and cancer. More particularly, the present invention relates to the use of proteins, peptides and biomolecules that bind to PAR-2 and inhibit the processes associated with the activation of that receptor.

In response to the Office Action dated November 15, 2006, Claims 1-7 are pending. No new matter has been added. Applicants submit the following remarks in an effort to address the rejections raised in the Office Action.

Elections and Restrictions

The Examiner has acknowledged Applicant's election of Group I, claims 21-30, now claims 1-7, in the reply filed June 30, 2006 responding to the Restriction Requirement. Applicants appreciate Examiner's acknowledgment.

Claim Rejections 35 U.S.C §112

In the Office Action dated November 15, 2006, the Examiner rejected Claims 3 under 35 U.S.C §112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. According to the Examiner, only the peptides disclosed in the specification, but not the full breadth of the claims "active fragments" meets the written description provision of 35 U.S.C §112, first paragraph.

Applicants respectfully traverse. Given the high level of skill in the art, together with the examples in the specification providing detailed methodology for assessing PAR activity, for the identification and testing of PAR-2 antagonists, Applicants respectfully submit that one skilled in the art would not experience undue experimentation in practicing the present invention commensurate in the scope of the claims. The specification specifically teaches how protein or peptide fragments may be identified (see paragraphs 0103-0105):

> [0103] Peptides or protein fragments comprising PAR antagonists can be produced as described above and tested for inhibitory activity using techniques and methods known to those skilled in the art. Full length proteins can be cleaved into individual domains or digested using various methods such as, for example, the method described by Enjyoji et al. (Biochemistry 34:5725-5735 (1995)).
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> [0104] Alternatively, fragments are prepared by digesting the entire protein, or large fragments thereof exhibiting anti-proliferative activity, to remove one amino acid at a time. Each progressively shorter fragment is then tested for anti-proliferative activity. Similarly, fragments of various lengths may be synthesized and tested for inhibitory activity. By increasing or decreasing the length of a fragment, one skilled in the art may determine the exact number, identity, and sequence of amino acids within the protein that are required for inhibitory activity using routine digestion, synthesis, and screening procedures known to those skilled in the art.
>
> [0105] Inhibitory activity is evaluated in situ by testing the ability of the proteins and peptides to inhibit the activation of PAR. Suitable assays are well known to skilled in the art and several examples of such are provided below in the Examples. Antiangiogenic activity may be assessed using the chick embryo chorioallantoic membrane (CAM) assay described by Crum et al., Science 230:1375 (1985) and described in U.S. Pat. No. 5,001,116, which is incorporated by reference herein. The CAM assay is briefly described as follows. Fertilized chick embryos are removed from their shell on day 3 or 4, and a methylcellulose disc containing the fragment of interest is implanted on the chorioallantoic membrane. The embryos are examined 48 hours later and, if a clear avascular zone appears around the methylcellulose disc, the diameter of that zone is measured. The larger the diameter of the zone, the greater the anti-angiogenic activity. Another suitable assay is the HUVEC assay.

In addition, the specification provides further guidance and support of the identification and testing of active fragment in the Examples: see for example, Examples 1-6.

Accordingly, in light of the foregoing remarks, reconsideration and withdrawal of the rejection of Claim 3 under 35 U.S.C §112, first paragraph is respectfully requested.

Claim Rejections 35 U.S.C §102

According to the Examiner, Claims 3 and 5 are rejected under 35 U.S.C §102(e) as being anticipated by Selberg et al. US 2003/0138388. The Examiner states that Selberg et al. disclose the peptide LIGK SEQ ID NO:3 (SEQ ID NO: 1 instantly claimed), see [0031] on page 2. Applicants respectfully submit that the Selberg et al. is specifically limited to the use of the disclosed compositions for purposes of increased pigment production and deposition *in vivo*. According to Selberg et al. US 2003/0138388 the compositions are provided in various embodiments for darkening the skin, mainly for cosmetic purposes. In contrast, the presently

claimed compositions are defined and claimed in accordance with their ability for inhibiting proteinase activated receptor activity comprising a protein, peptide, biomolecule or active fragment thereof.

Accordingly, in light of the foregoing remarks, reconsideration and withdrawal of the rejection of Claims 3 and 5 under 35 U.S.C §102(e) is respectfully requested.

Double Patenting

The Examiner has provisionally rejected Claims 3 and 5 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of co-pending Application No. 11/208,460. Applicants respectfully submit that co-pending Application No. 11/208,460 is directed to molecules have a specific structural components "A composition comprising a molecule; wherein the molecule comprises a first component, a linker and a second component; wherein the first component comprises a basic portion, a polar portion or a hydrogen-bonding portion; wherein the second component comprises a hydrophobic moiety." Applicants submit that the compositions of the present invention comprise LIGK (SEQ ID NO:1), LIGKV (SEQ ID NO:2), KGIL (SEQ ID NO:3), KGI (SEQ ID NO:4), AGI (SEQ ID NO:5), IGA (SEQ ID NO:6), KGA (SEQ ID NO:7), KGA (SEQ ID NO:8), KAI (SEQ ID NO:9), IAK (SEQ ID NO:10), RGI (SEQ ID NO:11), IGR (SEQ ID NO:12), Dab-GI (SEQ ID NO:13), Dap-GI (SEQ ID NO:14), IG-Dab (SEQ ID NO:15), IG-Dap (SEQ ID NO:16), LIG-Dab (SEQ ID NO:17), Dab-GIL (SEQ ID NO:18), LIG-Dap (SEQ ID NO:19), Dap-GIL (SEQ ID NO:20), LIG-Orn (SEQ ID NO:21), Orn-GIL (SEQ ID NO:22), Orn-GI (SEQ ID NO:23), IG-Orn (SEQ ID NO:24), ENMD 545, ENMD 547 or active fragments thereof. Though Applicants submit that the claims of present application are distinct from those of co-pending Application No. 11/208,460, upon the issuance of a Notice of Allowability, Applicants will consider submitting a Terminal Disclaimer to overcome the nonstatutory obviousness-type double patenting rejection.

Conclusion

The foregoing is submitted as a full and complete response to the Office Action mailed November 15, 2006, and early and favorable consideration of the claims is requested. If the Examiner believes any informalities remain in the application that may be corrected by Examiner's amendment, or there are any other issues which can be resolved by

telephone interview, a telephone call to the undersigned attorney at (404) 229-8566 is respectfully solicited.

Respectfully submitted,

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